

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

LOUISIANA WHOLESALE DRUG CO., INC.,
On Behalf of Itself and All Others Similarly
Situated,

Plaintiffs,

v.

SANOFI-AVENTIS, SANOFI-AVENTIS U.S.
LLC, and AVENTIS PHARMACEUTICALS
INC.,

Defendants.

Civil No. 07-cv-7343 (HB)

Hon. Harold Baer, Jr., U.S.D.J.
Hon. Andrew J. Peck, U.S.M.J.
ECF Case

**PLAINTIFF LOUISIANA DRUG CO. INC.’S OPPOSITION TO THIRD PARTY
SANDOZ INC.’S MOTION TO QUASH SUBPOENA**

Third Party Sandoz Inc. (“Sandoz”) has failed to establish that the subpoena issued by Plaintiff Louisiana Wholesale Drug Co. (“Louisiana Wholesale” or “Plaintiff”) should be quashed. Indeed, Sandoz’s Motion to Quash (“Motion”) acknowledges that Sandoz “has information that is relevant to this litigation and is perfectly willing to provide it.” Motion at 5. By Sandoz’s own admission, therefore, it should respond to the subpoena and produce the requested documents. At the very least, Sandoz should produce immediately documents responsive to the narrowed set of requests that Louisiana Wholesale has offered to accept for now, particularly in light of the aggressive schedule entered by Judge Baer in this case.¹ Similarly, Sandoz has also failed to

¹ Louisiana Wholesale offered to accept targeted and specific documents and data at this time in order to reduce Sandoz’s burden and to assist Louisiana Wholesale in meeting the rapidly-approaching deadlines for: a class certification motion (January 31, 2008), the end of fact discovery (May 1, 2008); and for opening expert reports (May 15, 2008). See

establish why it should not produce a corporate representative for a deposition on the topics covered by the subpoena. Accordingly, Sandoz's Motion should be denied.

I. NATURE OF THE ACTION

Louisiana Wholesale instituted this antitrust lawsuit against Defendants Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals Inc. ("Aventis" or "Defendants") as a result of Defendants' "sham" Citizen Petition to the Food & Drug Administration ("FDA"), which Defendants submitted for the sole purpose of unlawfully prolonging their monopoly over their drug Arava (generic name leflunomide). Defendants' "sham" Citizen Petition improperly delayed the FDA's approval of up to five Abbreviated New Drug Applications ("ANDA") filed by generic manufacturers to market less-expensive, generic leflunomide.

Specifically, Louisiana Wholesale has alleged that Defendants' "sham" petitioning delayed for up to five months FDA approval of some or all of the five generics -- *i.e.*, from March 31, 2005 (the date Defendants filed their Petition) until September 13, 2005 (the date the FDA emphatically denied Defendants' Petition, and approved each of the generic leflunomide products). During that period of delay, direct purchasers of Arava were forced to pay Defendants the high price for branded Arava, rather than the less expensive price for generic leflunomide. Similar cases have been before courts in this district. *See, e.g., In re Buspirone Patent Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002).

Declaration of Anne K. Fornecker, Esq in Opposition to Sandoz Inc.'s Motion to Quash ("Fornecker Decl.") at ¶¶ 6, 15, 18. Louisiana Wholesale offered to work with counsel for Sandoz to target additional specific documents thereafter if necessary. *Id.* at ¶ 19.

In the context of this antitrust lawsuit, Louisiana Wholesale bears the burden of demonstrating with evidence that one or more of the five generic companies: (a) would have received final FDA approval to their respective ANDAs prior to the date they actually received it; and (b) would have launched their cheaper generic versions of Arava on the market earlier than they actually did. The number of generic manufacturers that Louisiana Wholesale is able to demonstrate would have entered the market earlier “but for” Aventis’ improper petitioning activity, and the timing of the generics’ entry is, at a minimum, relevant to “causation,” and the amount of overcharge damages paid by Louisiana Wholesale and the direct purchaser class it seeks to represent.

II. FACTS RELATING TO THE SUBPOENA AND MOTION

The facts relating to Louisiana Wholesale’s subpoena and Sandoz’s Motion are set forth in the Fornecker Decl. In short, Louisiana Wholesale served substantively identical subpoenas on each of the five manufacturers that filed ANDAs to market generic leflunomide, seeking information and documents that are plainly relevant to Louisiana Wholesale’s claim. Louisiana Wholesale also served a subpoena on the generic manufacturer Defendants licensed to market an authorized generic leflunomide product. All but Sandoz are cooperating with Louisiana Wholesale to produce the required information, including Defendants’ licensee. Louisiana Wholesale attempted to reduce Sandoz’s purported burden by narrowing the scope of documents it is willing to accept at the present time, but Sandoz’s counsel was unwilling to accept the accommodation. Fornecker Decl. at ¶¶ 13-21. Instead, Sandoz filed this Motion.

III. SANDOZ HAS NOT ESTABLISHED THAT ITS BURDEN OUTWEIGHS LOUISIANA WHOLESALE'S NEED FOR THE REQUESTED DOCUMENTS

In deciding whether to quash a subpoena, courts weigh the burden to the subpoenaed party against the value of the information to the serving party. *See U.S. v. IBM Corp.*, 83 F.R.D. 97, 108 (S.D.N.Y. 1979). Whether a subpoena imposes a burden that outweighs the value to the serving party depends on “such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed.” *Id.*; *Jackson v. AFSCME LOCAL 196*, 2007 WL 3226310, at *1 (D. Conn. Oct. 30, 2007). “The burden of persuasion in a motion to quash a subpoena . . . is borne by the movant.” *Jones v. Hirschfeld*, 219 F.R.D. 71, 74-75 (S.D.N.Y. 2003) (citing *Dove v. Atl. Capital Corp.*, 963 F.2d 15, 19 (2d Cir. 1992)). As described below, Sandoz has not carried its burden.

Sandoz admits “that it has information that is relevant to this litigation.” *See Motion at 5*. However, Sandoz argues that Louisiana Wholesale’s subpoena is overly burdensome because much of the information requested by Louisiana Wholesale is “unrelated to any issue in the case.” *Id.* at 4. Sandoz is wrong.

As described in the Fornecker Decl., counsel for Louisiana Wholesale has explained to Sandoz its need for the requested documents - - all of which are relevant to Plaintiff’s claim. *See Maresco v. Evans Chemetics, Div. of W.R. Grace & Co.*, 964 F.2d 106, 114 (2d Cir.1992) (“The term ‘relevant’ should be construed broadly to encompass ‘any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.’”) (quoting *Oppenheimer Fund, Inc. v. Sanders*,

437 U.S. 340, 351 (1978)). *See also Horace Mann Ins. Co. v. Nationwide Mut. Ins. Co.*, 240 F.R.D. 44, 48 (D. Conn. 2007) (describing the threshold for establishing relevance as “Lilliputian”).

For example, Louisiana Wholesale requested from Sandoz documents that are relevant to establishing: (a) whether Sandoz would have been “ready, willing, and able” to come to market before the FDA denied Aventis’ petitioning activity, including, *e.g.*, its ANDA; communications with the FDA concerning the approvability of its ANDA; and Sandoz’s projections concerning when Sandoz expected to receive approval and launch its generic leflunomide product (*See* Fornecker Decl. at ¶ 9); and (b) antitrust impact and damages to the direct purchaser class it seeks to represent, including, *e.g.*, Sandoz’s electronically-maintained sales and pricing data;² and forecasts and projections of the unit and dollar sales Sandoz expected to make from launching generic leflunomide.³ *See* Fornecker Decl. at ¶ 10. Thus, Sandoz (and the other generic manufacturers) clearly possesses documents and electronically-stored sales data that meet the relevance threshold, and Sandoz has admitted as much in its Motion.

² Overcharge damages are predominantly measured as the difference between what class members actually paid for branded Arava, and what they would have paid for generic leflunomide, had it been on the market earlier. What class members would have paid for generic leflunomide, had it been on the market earlier, is determined by the prices class members actually paid for generic leflunomide once Aventis’ sham Petition was rejected by the FDA and the anticompetitive delay in generic competition ended.

³ Sandoz argues that it should not have to produce projections since they are mere “educated guesses.” Motion at 4. However, the fact that Sandoz uses “guesses” for business planning purposes does not diminish the relevance of this information. For example, Sandoz’s projections regarding when it expected to receive FDA approval are unmistakably relevant to whether Sandoz would have received FDA approval before the FDA denied Defendants’ petitioning activity. In addition, Sandoz’s forecasts regarding the leflunomide sales it would make after FDA approval are relevant to the savings direct purchasers of Arava could expect as a result of generic leflunomide competition.

Despite this, Sandoz argues that producing the bulk of the requested documents would be unduly burdensome based on its untested statements that Defendants' Petition delayed FDA approval of its generic leflunomide product by, at most, one day. *See* Motion at 3, 4, 5. However, a third party responding to a subpoena is not generally in a position to weigh the evidence regarding a plaintiff's claim, and Sandoz's depiction of its documents does not bear on the relevance of the information sought. Thus, Sandoz's characterization of its documents cannot support the Motion.

Sandoz has failed to offer any evidence to support its blanket assertion that producing the requested documents would be unduly burdensome. *See IBM Corp.*, 83 F.R.D. at 108 ("the burden of production must be compared with the size of and resources available to the responding party"); *id.* ("Any witness who is subpoenaed suffers inconvenience. . . . But this inconvenience, whether suffered by witnesses, grand jurors, or jurors, is part of the price we pay to secure the effective administration of justice and the enforcement of our laws.").

Louisiana Wholesale is seeking documents relating to a single ANDA filed by Sandoz. By definition, these documents cover a relatively limited time period, and are maintained in a limited number of files. The subpoena should not require Sandoz to search a large number of files in numerous locations, nor should the responsive documents be overly voluminous. Moreover, Louisiana Wholesale has already offered to narrow the set of documents it would presently seek - - in order to reduce the number of documents Sandoz must consider and produce. *See, e.g.*, Fornecker Decl. at ¶ 18. Thus, Sandoz's objection to producing this information appears disingenuous. As "one of the

largest prescription generic pharmaceutical companies in the U.S.”,⁴ Sandoz should not face a significant hardship in producing the requested information. *See IBM*, 83 F.R.D. at 108.

IV. SANDOZ HAS FAILED TO ESTABLISH THAT THE REQUESTED INFORMATION’S POTENTIAL PRIVILEGED OR PROPRIETARY NATURE JUSTIFIES QUASHING THE SUBPOENA

In support of its Motion, Sandoz asserts that it would be “unconscionable” to require it to expend any resources to review responsive information for privilege and to prepare a privilege log. Motion at 5. In effect, Sandoz asks this Court to exempt it from Fed. R. Civ. P. 45(d)(2)(A), which requires non-parties withholding responsive documents on the basis of privilege to prepare a privilege log. Such an argument is insufficient to quash Louisiana Wholesale’s subpoena. *Mid-Continent Casualty Co. v. Eland Energy, Inc.*, No. 3:7MC78, 2007 WL 948154, at *1 (D. Conn. March 26, 2007). In *Mid-Continent*, the court held that the fact that “subpoenaed documents might include some documents that are attorney-client privileged or subject to work product immunity is not a ground for quashing a Rule 45 subpoena.” *Id.* at *1. The court ordered the third party to produce the requested documents, withholding “only . . . those portions of documents as to which a *good faith* claim” of privilege was made, specifically identifying and describing each item withheld in a privilege log. *Id.* (emphasis in original).

Similarly, Sandoz’s allusion to the “proprietary” nature of some of the requested documents is also insufficient to quash Louisiana Wholesale’s subpoena. *See Nova Products, Inc. v. Kisma Video, Inc.*, 220 F.R.D. 238, 241 (S.D.N.Y. 2004) (finding no “compelling reason” to quash subpoena based on claim that requested information was

⁴See Sandoz’s website at http://www.us.sandoz.com/site/en/company/profile/fact_sheet/content.shtml.

“proprietary and confidential”). This is particularly true here, where the protective order that has been entered by the Court applies to third parties. *See Protective Order*, attached as Fornecker Decl. Ex. 3.

V. SANDOZ HAS FAILED TO ESTABLISH THAT THE SUBPOENA SHOULD BE QUASHED BECAUSE ITS LIKELY WITNESS RESIDES IN COLORADO

Sandoz revealed for the first time in its Motion that the individual whom it would likely designate as a corporate witness and many of the responsive documents are located in Colorado. However, these facts do not establish a basis for quashing the subpoena for two reasons.

First, Plaintiff served the subpoena on Sandoz at its headquarters in Princeton, New Jersey, which is within 100 miles of this Court and thus within the Court’s jurisdiction.⁵ Moreover, contrary to the assertion in Sandoz’s Motion, both the subpoena and the Notice provide for the deposition to take place in New York City, or at a place “mutually agreed” upon by Plaintiff and Sandoz. Sandoz never attempted to seek an agreement with Plaintiff regarding the location of the deposition.

Second, to quash the subpoena and avoid producing a corporate representative for deposition, Sandoz would have to prove that the testimony of the proposed deponent would not be relevant to any issue in this case. *American High-Income Trust v. AlliedSignal, Inc.*, No. 02Civ.2506, 2006 WL 3545432 at *3 (S.D.N.Y. Dec. 8, 2006) (denying motion to quash). *See also Jones v. Hirschfeld*, 219 F.R.D. at 74 (noting that “it is exceedingly difficult to demonstrate an appropriate basis for an order barring the taking

⁵ See Sandoz’s website at <http://www.us.sandoz.com/site/en/company/profile/locations/content.shtml> (“The headquarters for Sandoz U.S. is located in Princeton, New Jersey.”).

of a deposition"). Sandoz does not contend that its witness's testimony would be irrelevant. To the contrary, Sandoz admits it has information relevant to the lawsuit and is willing to provide it - - although Sandoz has refused to cooperate thus far.

Because the subpoena: (1) was properly served on Sandoz within 100 miles of this Court; (2) provides that the deposition may take place in a location mutually agreed by the parties; and (3) seeks admittedly relevant information, Sandoz has failed to establish that this Court should deny Louisiana Wholesale the opportunity to depose Sandoz's corporate representative.

VI. CONCLUSION

Sandoz has failed to carry its burden to show why Louisiana Wholesale's subpoena should be quashed. Louisiana Wholesale respectfully requests that the Court deny Sandoz's Motion and allow Louisiana Wholesale to pursue the requested discovery.

December 6, 2007

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CERTIFICATE OF SERVICE

I, Anne K. Fornecker, do hereby certify that on December 6, 2007, I served the foregoing PLAINTIFF LOUISIANA WHOLESALE DRUG CO. INC.'S OPPOSITION TO THIRD PARTY SANDOZ, INC.'S MOTION TO QUASH SUBPOENA on the following attorneys, in the manner specified below:

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